

**REMARKS**

Entry of the foregoing, reexamination and reconsideration of the above-identified application are respectfully requested.

A Supplemental Amendment was filed on June 6, 2003, and a Second Supplemental Amendment was filed on August 14, 2003. Neither of these amendments were entered by the Examiner. Advisory Actions were issued on August 8 and September 2, 2003. The instant Amendment is being filed to incorporate helpful suggestions raised by the Examiner in the September 2<sup>nd</sup> Advisory Action into the previously presented claims.

The new claims are directed to an isolated monoclonal antibody "which recognize a 150 kDA *T. equigenitalis* protein." The claims also include claims directed to embodiments wherein additional antibodies are included with the antibody against the 150 kDA protein. In particular, monoclonal antibodies which recognize *T. equigenitalis* proteins selected from the group consisting of *T. equigenitalis* proteins of 120 kDA, 52.7 kDA and 22 (LPS) kDA may also be included in accordance with the teachings of the specification.

Dependent claims have been added directed to strains of hybridomas, methods of identification of a *T. equigenitalis* bacterium and of diagnosing a *T. equigenitalis* infection, and kits comprising the claimed antibodies. These claims mirror those already pending, and thus are fully supported by the specification.

No new matter is added by the instant amendment. The new claims were written in accordance with the Examiner's suggestion to be directed to monoclonal antibodies which recognize a 150 kDA *T. equigenitalis* protein. As noted by the Examiner during the

personal interview, none of the cited art teaches a monoclonal antibody which recognizes the 150 kDA epitope. Antibodies or compositions including such antibodies which recognize a 150 kDA epitope of *T. equigenitalis* would not be anticipated by or obvious in view of the prior art. Withdrawal of the rejections of record is thus respectfully requested and believed to be in order.

Applicants further note that the recitation of "150 kDA" is not an exact value, but would be recognized in the art as including some variability. As described in the specification, the value of "150 kDA" was determined using gel electrophoresis. This value thus inherently includes some variability, i.e.,  $\pm 10\%$ . A person skilled in the art would thus recognize that the claim includes antibodies which recognize a *T. equigenitalis* protein of 150 kDA  $\pm 10\%$ .

In view of the instant amendments, the pending rejections of record are believed to be overcome. In the September 2<sup>nd</sup> Advisory Action, the Examiner indicated that claims 40, 41, 43, 45, 47, 48, 50-52, 54-57, 64, 66, 74 and 76 would be allowable. With respect to claim 42 and claims 58-63, 65, 66, 67, 68, 70, 75, 77 and 78 (all of which depend from claim 42), these claims should also now be allowable. Claim 42 is written in accordance with the Examiner's helpful suggestion at page 2.

Claim 44 should also now be allowable since it now recites that the hybridoma secretes the monoclonal antibody of claim 40. Claim 63 has been similarly amended.

Claims 46, 69, 71, 72 and 73, as well as claims dependent therefrom, should also now be allowable since the method steps have been written to more clearly define the steps

in accordance with the Examiner's comments on page 3, paragraph (e) of the Advisory Action.

Claims 49 and 79-83 are presented directed to pharmaceutical compositions. Such claims are enabled by the specification. The specification describes pharmaceutical compositions as well as vaccine compositions at page 7, line 31 - page 8, line 15 as follows:

According to another advantageous embodiment of the invention, the AcM and their fragments defined above can be used therapeutically for combating an infection by *T. equigenitalis*, and more particularly against contagious equine metritis.

The invention thus also relates to pharmaceutical compositions containing one or more AcM, or their fragments, defined above, as vectors of medication or as agents of passive immunotherapy, alone or in conjunction with pharmaceutically inert vehicles. It also relates to their use for the production of biosensors.

According to yet another embodiment, the invention relates to the use of immunogenic proteins and anti-AcM or their fragments for the preparation of vaccinal compositions for preventing infection by *T. equigenitalis*.

The vaccinal compositions of the invention are characterized in that they contain at least one immunogenic protein or one anti-AcM or their fragments, as defined above, in sufficient quantity to produce an immune response, in combination with physiologically acceptable excipients.

Example 6 describes how to prepare anti-*T. equigenitalis* antibodies and how to prepare a vaccine containing same. Based upon these descriptions in the specification, one skilled in the art would be enabled to make and use a pharmaceutical composition. Due to the specificity of the monoclonal antibodies of the invention, one skilled in the art would appreciate that such monoclonal antibodies could be used as pharmaceutical compositions. Claims 49 and 79-83 are thus believed to be fully enabled.

It is respectfully submitted that all prior rejections have been overcome by the above amendments and that all of the pending claims are in condition for allowance. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (650) 622-2360 so that prosecution of the application may be expedited.

Respectfully submitted,

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